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EXAMINER	
SCHILLINGER, ANN M	

ART UNIT	PAPER NUMBER
3774	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/777,411	GORDON ET AL.	
	Examiner	Art Unit	
	ANN SCHILLINGER	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 November 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-39 and 41-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-39 and 41-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :11/20/09,11/20/09,11/20/09,11/20/09,11/20/09,11/20/09,12/28/09, 2/3/10.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27-34, 37, 38, 43, 48, and 49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not adequately explain how the expansion member lowers the support surface of the first insert below and away from the inferior surface of the cage element.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15-17, 19-23, 25-29, 32-34, 39, and 41-50 are rejected under 35 U.S.C. 102(b) as being anticipated Vaccaro (US Pat. No. 6,102,950). Vaccaro discloses the following of claim 15: an intervertebral implant for a human spine, comprising: a cage element (20) comprising a superior surface and an inferior surface (Fig. 2), wherein the inferior surface of the cage element is configured to support a first vertebra of the human spine to inhibit movement of the first

vertebra towards a second vertebra, and wherein the superior surface of the cage element comprises a first opening; an insert (50) comprising a support surface for the second vertebra, wherein the support surface configured to, during use, supports at least a portion of the second vertebra above and away from the superior surface of the cage element and inhibits movement of the second vertebra towards the first vertebra, and wherein the insert, during use, is configured to be positioned at least partially in the cage element; and an expansion member (40) configured to be that, during use, is inserted in the cage element through an opening (70) in a side of the cage element to expand the intervertebral implant by elevating the insert to move a portion of the insert through the first opening in the superior surface of the cage element so that at least a portion of the support surface of the insert is raised relative to the inferior above and away from the superior surface of the cage to support at least a portion of the second vertebra above and away from the superior surface of the cage element (col. 6, lines 27-41; col. 7, lines 15-64).

Vaccaro discloses the following of claim 16: the intervertebral implant of claim 15, wherein the intervertebral implant is configured such that the direction of movement of the expansion member is substantially perpendicular to the direction of movement of the insert (Fig. 7)

Vaccaro discloses the following of claim 17: the intervertebral implant of claim 15, wherein the expansion member is configured to be advanced between an interior surface of the cage element and the inferior surface of the insert (Fig. 7).

Vaccaro discloses the following of claim 19: the intervertebral implant of claim 15, wherein an interior surface of the cage element comprises a raised portion (52) configured to inhibit backout of the expansion member after expansion of the intervertebral implant.

Vaccaro discloses the following of claim 20: the intervertebral implant of claim 15, wherein the expansion member comprises an angled portion (top and bottom surfaces of element 40) configured to engage an angled portion of the insert to facilitate insertion of the expansion member in the cage element (Fig. 7).

Vaccaro discloses the following of claim 21: an intervertebral implant for a human spine, comprising: a cage element (20) comprising a superior surface and an inferior surface (Fig. 2), wherein the inferior surface of the cage element is configured to support a first vertebra of the human spine to inhibit movement of the first vertebra towards a second vertebra, and wherein the superior surface of the cage element comprises an opening (26); an insert (50) comprising an inferior surface and a support surface for the second vertebra, wherein the support surface configured to, during use, supports the at least a portion of the second vertebra above and away from the superior surface of the cage element and inhibits movement of the second vertebra towards the first vertebra, wherein the insert, during use, is configured to be positioned in the cage element such that at least a portion of the inferior surface of the insert is inside below the superior surface of the cage element and at least a portion of the support surface of the insert is outside above the superior surface of the cage element to support at least a portion of the second vertebra above and away from the superior surface of the cage element (Fig. 7; col. 6, lines 27-41; col. 7, lines 15-64); and an expansion member (40) configured to be that, during use, is inserted in the cage element through an opening (70) in a side of the cage element to elevate at least a portion of the insert through the opening in the superior surface of the cage element so that the support surface of the insert is raised relative to the inferior above and away from the

superior surface of the cage to support at least a portion of the second vertebra above and away from the superior surface of the cage element (Fig. 7).

Vaccaro discloses the following of claim 22: the intervertebral implant of claim 21, wherein the intervertebral implant is configured such that the direction of movement of the expansion member is substantially perpendicular to the direction of movement of the insert (Fig. 7).

Vaccaro discloses the following of claim 23: the intervertebral implant of claim 21, wherein the expansion member is configured to be advanced between an interior surface of the cage element and the inferior surface of the insert (Fig. 7).

Vaccaro discloses the following of claim 25: the intervertebral implant of claim 21, wherein an interior surface of the cage element comprises a raised portion (52) configured to inhibit backout of the expansion member after insertion of the expansion member.

Vaccaro discloses the following of claim 26: the intervertebral implant of claim 21, wherein the expansion member comprises an angled portion (top and bottom surfaces of element 40) configured to engage an angled portion of the insert to facilitate insertion of the expansion member in the cage element (Fig. 7).

Vaccaro discloses the following of claim 27: the intervertebral implant for a human spine, comprising: a cage element (20) with a superior surface and an inferior surface (Fig. 2), wherein the inferior surface of the cage element comprises a first opening (where elements 50 pass through) and the superior surface of the cage element comprises a second opening (26); a first insert (lower elements 50), wherein, during use, at least a portion of the first insert is configured to be positioned in the cage element proximate the first opening, and wherein the first

insert comprises a support surface that, during use, supports at least a portion of a first vertebra below and away from the inferior surface of the care element and inhibits movement of the first vertebra towards a second vertebra; a second insert (upper elements 50), wherein, during use, at least a portion of the second insert is configured to be positioned in the cage element proximate the second opening, and wherein the second insert comprises a support surface that, during use, supports at least a portion of a second vertebra above and away from the superior surface of the cage element and inhibits movement of the second vertebra towards the first vertebra (Fig. 7); and an expansion member (40) during use, is inserted in a third opening (70) in the cage element to lower the support surface of the first insert relative to below and away from the inferior surface of the cage element (Fig. 7) wherein the support surface of the first insert is configured to couple to a first vertebra to support at least a portion of the first vertebra below and away from the inferior surface of the cage element and inhibit movement of the first vertebra towards a second vertebra; wherein the expansion member when inserted in the third opening raises the support surface of the second insert relative to above and away from the superior surface of the cage element, wherein the support surface of the second insert is configured to couple to the second vertebra to support at least a portion of the second vertebra above and away from the superior surface of the cage element and inhibit movement of the second vertebra towards the first vertebra (Fig. 7; col. 6, lines 27-41; col. 7, lines 15-64).

Vaccaro discloses the following of claim 28: the intervertebral implant of claim 27, wherein the intervertebral implant is configured such that the direction of movement of the expansion member is substantially perpendicular to the direction of movement of the first insert and the second insert (Fig. 7).

Vaccaro discloses the following of claim 29: the intervertebral implant of claim 27, wherein the expansion member is configured to be advanced between a superior surface of the first insert and an inferior surface of the second insert (Fig. 7).

Vaccaro discloses the following of claim 32: the intervertebral implant of claim 27, wherein an interior surface of the cage element comprises a raised portion (52) configured to inhibit backout of the expansion member after insertion of the expansion member.

Vaccaro discloses the following of claim 33: the intervertebral implant of claim 27, wherein expanding the intervertebral implant comprises increasing a height of the intervertebral implant (Fig. 7).

Vaccaro discloses the following of claim 34: the intervertebral implant of claim 27, wherein the expansion member comprises at least one angled portion (sloped, upper portion of element 40) configured to engage an angled portion of the first insert to facilitate insertion of the expansion member in the cage element (Fig. 7).

Vaccaro discloses the following of claim 39: an intervertebral implant for a human spine, comprising: a first member (upper elements 50) comprising a first inferior surface and a first superior surface, where the first superior surface comprises a substantially planar surface configured to contact and support a first vertebrae of a human spine; a second member (lower elements 50) comprising a second inferior surface and a second superior surface, where the second inferior surface comprises a substantially planar surface configured to contact and support a second vertebrae of a human spine; a cage (20) comprising a first opening (26) in a superior surface of the cage and a second opening (where lower elements 50 pass through) in an inferior surface of the cage, wherein, during use, the first member is at least partially disposed in

the first opening and the second member is disposed at least partially in the second opening (Fig. 2, 7); and an expansion element (40) configured to be that, during use, is inserted between the first inferior surface of the first member and the second superior surface of the second member, wherein insertion of the expansion member is configured to expands the first and second members relative to one another to increase a separation distance between the first superior surface of the first member and the second inferior surface of the second member, wherein the first superior surface is expanded above the superior surface of the cage and the second inferior surface is expanded below the inferior surface of the cage, such that the distance between the first superior surface and the second inferior surface is greater than the distance between the superior surface and the inferior surface of the cage, and wherein the first superior surface supports at least a portion of the first vertebra above the superior surface of the cage and the second inferior surface supports at least a portion of the second vertebra below the inferior surface of the cage (Fig. 7; col. 6, lines 27-41; col. 7, liens 15-64).

Vaccaro discloses the following of claim 41: the intervertebral implant of claim 15, wherein the support surface comprises a substantially planar surface that supports at least a portion of the second vertebra above and away from the superior surface of the cage element and inhibits movement of the second vertebra towards the first vertebra during use contacts the second vertebra (Fig. 7).

Vaccaro discloses the following of claim 42: the intervertebral implant of claim 21, wherein the support surface comprises a substantially planar surface that supports at least a portion of the second vertebra above and away from the superior surface of the cage element and

inhibits movement of the second vertebra towards the first vertebra during use contacts the second vertebra (Fig. 7).

Vaccaro discloses the following of claim 43: the intervertebral implant of claim 27, wherein the support surface of the first insert comprises a substantially planar surface that supports at least a portion of the first vertebra above and away from the inferior surface of the cage element and inhibits movement of the second vertebra towards the first vertebra during use, and wherein the support surface of the second insert comprises a substantially planar surface that supports at least a portion of the second vertebra above and away from the superior surface of the cage element and inhibits movement of the second vertebra towards the first vertebra during use contacts the second vertebra (Fig. 7).

Vaccaro discloses the following of claim 26: the intervertebral implant of claim 15, wherein the support surface of the insert comprises a substantially planar surface of sufficient cross-sectional area to support the second vertebra above and away from the superior surface of the cage element during use (Fig. 7).

Vaccaro discloses the following of claim 45: the intervertebral implant of claim 15, wherein, during use, the support surface of the insert supports the second vertebra above and away from the superior surface of the cage element such that the second vertebra does not contact the superior surface of the cage element (Fig. 7).

Vaccaro discloses the following of claim 46: the intervertebral implant of claim 21, wherein the support surface of the insert comprises a substantially planar surface of sufficient cross-sectional area to support the second vertebra above and away from the superior surface of the cage element during use (Fig. 7).

Vaccaro discloses the following of claim 47: the intervertebral implant of claim 21, wherein, during use, the support surface of the insert supports the second vertebra above and away from the superior surface of the cage element such that the second vertebra does not contact the superior surface of the cage element (Fig. 7).

Vaccaro discloses the following of claim 48: the intervertebral implant of claim 27, wherein the support surface of the first insert comprises a substantially planar surface of sufficient cross-sectional area to support the second vertebra below and away from the inferior surface of the cage element during use, and wherein the support surface of the second insert comprises a substantially planar surface of sufficient cross-sectional area to support the second vertebra above and away from the superior surface of the cage element during use (Fig. 7).

Vaccaro discloses the following of claim 49: the intervertebral implant of claim 27, wherein, during use, the support surface of the first insert supports at least a portion of a first vertebra below and away from the inferior surface of the cage element such that the first vertebra does not contact the inferior surface of the cage element, and the support surface of the second insert supports at least a portion of a second vertebra above and away from the superior surface of the cage element such that the second vertebra does not contact the superior surface of the cage element (Fig. 7).

Vaccaro discloses the following of claim 50: an intervertebral implant, comprising: a cage element (20) implanted between a first vertebra and a second vertebra during use, wherein the cage element comprises a first surface (upper surface) facing the first vertebra and a second surface (lower surface) facing the second vertebra when implanted; and a means (40, 50) for supporting the first vertebra in a position away from the first surface of the cage element.

Please note that claim language such as "adapted to/for" and "configured to/for" is functional language. In order to be given patentable weight, a functional recitation must be supported by recitation in the claim of sufficient structure to warrant the presence of the functional language.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 18, 24, 30, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vaccaro in view of Sertich (U.S. Pat. No. 5,800,550). Vaccaro teaches the invention substantially as claimed, however, Vaccaro does not teach an osteoconductive mesh structure on the insert's support surface. Sertich teaches an intervertebral implant with an osteoconductive mesh structure in col. 4, lines 17-21 for the purpose of promoting bone ingrowth and fusion. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Vaccaro to include an osteoconductive mesh in order to promote bone ingrowth and fusion.

Claims 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vaccaro. Vaccaro discloses the claimed invention except for the support surface covering a majority of the implant. It would have been an obvious matter of design choice to make the support surface cover a majority of the implant, since such a modification would have involved a mere change in

the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose,* 105 USPQ 237 (CCPA 1955).

Response to Arguments

In view of the amendments submitted on 4/21/2009, the 35 U.S.C. 112 rejections are withdrawn.

Applicant's arguments filed 4/21/2009 have been fully considered but they are not persuasive. The Applicant contends that Vaccaro does not disclose a support surface configured to support a vertebra. The examiner respectfully disagrees. Vaccaro discloses support surfaces in elements 50 that are inserted against the superior and inferior vertebra (please see Fig. 1). These surfaces are sufficient to support "at least a portion of" the vertebra they are in contact with, and by its physical presence, they surfaces inhibit movement of the vertebra towards each other.

The Applicant also contends that Vaccaro does not disclose an expansion member that is inserted into the cage element in order to expand the intervertebral implant. The examiner respectfully disagrees. Vaccaro discloses in columns 6-7 and in Figure 7, that element 40 is inserted into and used to expand element 20, thus meeting the claims' limitations.

The Applicant further contends that Vaccaro does not disclose inserts that are positioned such that during use at least a portion of the inserts are above and below the superior and the inferior surfaces of the cage element, respectively. The examiner respectfully disagrees. Vaccaro discloses in Figures 1 and 7, that the inserts (upper and lower elements 50) are located above and below the superior and the inferior surfaces of the cage element, respectively.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANN SCHILLINGER whose telephone number is (571)272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on (571) 272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. S./
Examiner, Art Unit 3774

/DAVID ISABELLA/
Supervisory Patent Examiner, Art Unit 3774